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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 180

[Docket No. 2004F–0066]

Food Additives Permitted in Food on an Interim Basis or in Contact With Food Pending Additional Study; Mannitol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to permit the manufacture of mannitol by fermentation of sugars such as fructose, glucose, or maltose by the action of the microorganism *Lactobacillus intermedius* (*fermentum*). This action is in response to a petition filed by zuChem, Inc.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**]. Submit written or electronic objections and requests for a hearing by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: You may submit written objections and requests for a hearing, identified by Docket No. 2004F–0066, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004F–0066 in the subject line of your e-mail message.

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- FAX: 301–827–6870.

- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the "Objections" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1282.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of February 19, 2004 (69 FR 7759), FDA announced that a food additive petition (FAP 4A4754) had been filed by zuChem, Inc., c/o Hyman, Phelps and McNamara, P.C., 700 13th Street NW., Washington, DC 20005. The petition proposed to amend the food additive regulations in § 180.25 *Mannitol* (21 CFR 180.25) to permit the manufacture

of mannitol by fermentation of sugars such as fructose, glucose, and maltose by the action of the microorganism *L. intermedius* (*fermentum*).

In 1973, the agency proposed to affirm mannitol as generally recognized as safe (GRAS) based on the findings by the Select Committee on GRAS Substances from the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (38 FR 20046, July 26, 1973). In response to the proposal, the agency received comments, including information raising questions about the safety of mannitol. Rather than affirm the GRAS status of mannitol, the agency instead decided to establish an interim food additive regulation for mannitol, pending additional study of the ingredient (39 FR 34178, September 23, 1974) and based on the conclusion that there would be no increased risk to the public health to continue existing uses and levels of use of mannitol while additional studies were carried out. The regulation was subsequently amended (61 FR 7990, March 1, 1996) to permit the manufacture of mannitol by fermentation of sugars or sugar alcohols by the action of the yeast *Zygosaccharomyces rouxii.*

The proposed fermentation organism, *L. fermentum,* is currently used in various food applications. For example, strains of *L. fermentum* are used in sourdough bread and pressed curd cheeses, and FDA has affirmed as GRAS a urease preparation from *L. fermentum* for use in the manufacture of wine. The petitioner has submitted data in support of the microbiological safety of mannitol produced by this bacterium. In addition, the petitioner has provided detailed information on the process used to produce mannitol by this fermentation method, including information on the purification steps that are used. FDA concludes, having considered the evidence concerning the production organism and the purification procedures, that *L. intermedius*

(*fermentum*) will not be present in the final product and can be safely used in the fermentation of fructose and other sugars to produce mannitol provided that the purity of the culture is maintained, and that a nonpathogenic, nontoxicogenic strain of *L. intermedius* (*fermentum*) is used (Ref. 1).

II. Conclusion

The current interim regulation for mannitol specifies manufacturing procedures that do not include the proposed fermentation process. FDA has reviewed data and information in the petition on the chemical equivalence of mannitol produced using *L. intermedius* (*fermentum*) and mannitol produced by the currently-regulated methods. Based on its review, the agency concludes that mannitol manufactured by fermentation of sugars by the action of *L. intermedius* (*fermentum*) is equivalent to mannitol produced by the currently-regulated methods as described in § 180.25. In addition, mannitol manufactured by the proposed fermentation process will have the same intended technical effect and uses as mannitol produced by the currently-regulated methods. Consequently, there will be no change in exposure to mannitol (Refs. 2 and 3). Therefore, FDA concludes that § 180.25 should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 4A4754. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections (see **DATES**). Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response

to the regulation may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA memorandum from P. C. DeLeo, Division of Petition Review, to C. Johnston, Division of Petition Review, April 21, 2004.

2. FDA memorandum from D. E. Folmer, Division of Petition Review, to C. Johnston, Division of Petition Review, April 20, 2004.

3. FDA memorandum from D. E. Folmer, Division of Petition Review, to C. Johnston, Division of Petition Review, July 29, 2004.

List of Subjects in 21 CFR Part 180

Food additives.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 180 is amended as follows:

PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL STUDY

■ 1. The authority citation for 21 CFR part 180 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371; 42 U.S.C. 241.

■ 2. Section 180.25 is amended by adding paragraph (a)(3) to read as follows:

§ 180.25 Mannitol.

(a) * * *

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(3) A pure culture fermentation of sugars such as fructose, glucose, or maltose using the nonpathogenic, nontoxicogenic bacterium *Lactobacillus intermedius* (*fermentum*).

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Dated: 10/27/04
October 27, 2004.

Leslye M. Fraser,
Director,
Office of Regulations and Policy,
Center for Food Safety and Applied Nutrition.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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